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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,793	01/25/2006	Wolfgang Lechner	U 016099-9	7527
140	7590	06/29/2006	EXAMINER	
LADAS & PARRY 26 WEST 61ST STREET NEW YORK, NY 10023			HOPKINS, CHRISTINE D	
			ART UNIT	PAPER NUMBER
			3735	

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/565,793

Applicant(s)

LECHNER, WOLFGANG

Examiner

Christine D. Hopkins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>25 January 2006</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Objections

1. The claims include reference characters which are enclosed within parentheses. The use of reference characters is considered as having no effect on the scope of the claims. Since the reference characters are not afforded patentable weight, the reference characters enclosed within parentheses apparently should be deleted from the claims. Correction is requested.

2. Claims 7, 10-12, and 14-15 are objected to because of the following informalities: at claim 7, line 2 the phrase "a device for pumping liquid liquid" is improper;

At line 2 of claims 10-11, "the" should be deleted; at line 2 of claim 12, "the" (first occurrence) should be deleted; at line 2 of claim 14, "the" should read --a--; and at line 3 of claim 15, "the" (first occurrence) should read --an--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 at lines 2 and 4, and claim 2 at lines 2 and 4 recite the limitation “the stoma side.” There is insufficient antecedent basis for this limitation in the claims. In addition, at line 6 of claim 1, it is unclear which chamber is “the one chamber” and which is “the other chamber.” At line 6 of claim 2 it is unclear which chamber is “the other chamber.”

Claims 2-5, 7, 15-20 recite the limitation “stoma-restricting chamber.” There is insufficient antecedent basis for the limitation in these claims.

Claims 2, 5, 13 and 22 recite the limitation “the sensory chamber.” There is insufficient antecedent basis for the limitation in these claims.

Claims 7, 15, and 17-20 recite the limitation “the reservoir.” There is insufficient antecedent basis for the limitation in these claims.

Claim 15 recites the limitation “the detection device.” There is insufficient antecedent basis for the limitation in this claim.

Regarding claim 9, the phrase “for instance” renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 19 recites “the stomach-restricting chamber.” This limitation lacks antecedent basis and should apparently read –the stoma-restricting chamber--.

Regarding claim 24, at line 3, it is unclear which of the plurality of chambers the limitation “said chamber” is intended to refer to.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 5-6 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 5 recites "the sensory chamber being arranged on the gastric wall." This recites a positive relationship to the human body. However, the human body is non-statutory subject matter and cannot be positively recited. Therefore, Applicant should amend the claim to recite --the sensory chamber adapted to be arranged on the gastric wall--.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Imran et al. (U.S. Patent No. 7,037,343). Imran teaches an implantable stomach prosthesis, composed of expandable members, for controlling passage of food from the stomach to the small intestine. In reference to claim 1, the device of Imran comprises an outer support member (element 31), or "nonextensible back" made of an inelastic material for

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purposes of structural support. It further constitutes two "chambers," one being the section of inflatable members (elements 36a-g) and the other "chamber" being the pyloric valve (element 38), or "stoma-restricting chamber," for increasing or decreasing the diameter of the lower portion of the stomach (see Fig. 1A and 1B). The pyloric valve, or "stoma-restricting chamber," relaxes by partially deflating the inflation member section, or "first chamber," thus placing the chambers in fluid communication with each other (col. 7, lines 15-20).

With respect to claim 2, sensors 53 and 54 on the device of Imran are located on opposite ends of the pyloric valve, or "second chamber," for sensing pressure on either side of the valve (col. 7, lines 8-14). The device further includes a pump system that comprises a reservoir of sterile inflation medium for inflating the expandable members, or "chambers," in response to pressure detected by the sensors (col. 2, lines 41-48 and col. 3, lines 2-4). In view of claim 3, the "chambers" of Imran are arranged next to each other (element 38 and elements 36a-g) as depicted in Fig. 1B. The "stoma-restricting chamber," or pyloric valve (element 38), is located at the aborad end portion of the stomach prosthesis (col. 6, lines 7-9).

In reference to claim 4, the device of Imran is subdivided into communicating chambers or sections, elements 36a-g, which establish the boundaries of the pyloric valve, or "stoma-restricting chamber" (col. 5, lines 55-60), as depicted in Fig. 1B.

Imran provides, with respect to claims 5 and 6, a "stoma-restricting chamber," or pyloric valve (element 38), and inflation member section (36g of Fig. 1B), or "sensory chamber," containing sensors 53 and 54, arranged one above the other with the

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sensors located on the gastric wall. A "layer" or inner member (element 32) is provided between the chambers.

In view of claim 7, the system of Imran includes an implantable pump system to inflate and deflate the "chambers" or inflatable member sections 36a-g, the pump system having an intake that is coupled to a fluid reservoir (col. 6, lines 40-44). With respect to claim 8, the pump of Imran is a DC powered pump. Likewise, in view of claim 9, the pump system of Imran may contain a hydraulic pump (col. 6, lines 46-50).

In reference to claims 10-13, the sensors of Imran (elements 53 and 54 of Fig. 1B), located along the gastric wall, detect eating and swallowing activity by sensing pressure on either side of the pyloric valve. The sensors are further coupled to an electronics unit (element 50), or "electronic circuit" (col. 7, lines 8-17).

With respect to claim 14, the device of Imran comprises a controller for controlling the function of peristaltic movement and sensors that may direct the function of peristaltic movement (col. 3, lines 40-51).

In reference to claim 15, the "detection device," or sensors (elements 53 and 54) of Imran trigger activity within the "sensory chamber," or inflation member section 36g, by inflating or deflating the sections via the pump system and subsequently tighten or relax the "stoma-restricting chamber" or pyloric valve. This process can be reversed, and the inflation medium is pumped back out of the pyloric valve and inflation member section, and back into the reservoir (col. 9, lines 5-15).

With respect to claim 16, the "chambers" of Imran (the inflatable member section 36a-g and the pyloric valve 38) are connected with each other via "an auxiliary

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chamber" or reservoir (element 49 contained within the dashed box of Fig. 1B). The transport of liquid can occur from the "second chamber" or inflatable member section to the "auxiliary chamber" or reservoir via a valve (elements 46a-f) as depicted in Fig. 1B1, and a further valve (element 46g) connecting the "stoma-restricting chamber," or pyloric valve (element 38), to the "auxiliary chamber," or reservoir, for allowing liquid transport.

In reference to claim 17, Imran teaches two separate reservoirs which will be construed as the "auxiliary chamber" and "reservoir" for the purposes of examination since "the reservoir" of the instant application lacks proper antecedent basis. One reservoir of Imran (element 58), or the "auxiliary chamber," functions as a chamber for delivery of a material (col. 8, lines 26-29) such as air. This reservoir is located between the other "reservoir" of Imran (element 49) and the "stoma-restricting chamber," or pyloric valve (element 38), which constitutes the far right portion of Fig 1B1.

With respect to claim 18, a device for carrying out liquid exchange (contained within the dashed box of Fig. 1B) is provided for by Imran between the "stoma-restricting chamber," or pyloric valve (element 38), and the "second chamber," or inflation member section (element 36a-g), via the outer tube, element 31, (col. 7, lines 61-67) which houses elements 55a-f, and conduit 56, which is a part of the inner member, element 32, as depicted in Fig. 1B (col. 8, lines 26-33). Furthermore, in reference to claim 19, the "common partition wall," or inner member 32, of Imran is arranged between the chambers (Fig. 1B) and comprises a flexible material such as polyethylene, which is "microporous" (col. 6, lines 9-11).

In view of claims 20 and 21, the bi-directional pump of Imran may be configured in a number of ways, thus concluding its allowance of backflow controlled by a series of valves that direct fluid in and out of the reservoir and to the individual chambers (col. 6, lines 43-50).

In reference to claim 22, the "sensory chamber," or inflation member section of Imran, is connected to a pressure transducer (element 48), or "device emitting electric pulses," that senses pressure within the stomach and thereby inflates the inflatable member section to initiate a sequence of mixing food and emptying the stomach (col. 8, lines 44-57).

With respect to claim 23, the "further liquid-filled chamber," or inner member (element 32) of Imran, comprises a thin-walled, flexible material that adapts to the dimensions of the device as depicted in Fig. 1B (col. 6, lines 9-13), and further floats loosely within the outer member support (element 31) in order to permit movement of the inflatable member sections 36a-g (col. 6, lines 21-26). In reference to claim 24, the "further liquid-filled chamber," or inner member 32 of Imran, is connected to a port (element 57) for delivery of a material such as an antibiotic (col. 8, lines 26-29).

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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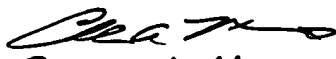
U.S. Patent No. 4,399,809 to Baro et al. discloses an apparatus to be applied to a stoma within the body, comprised of chambers to be inflated or deflated with a fluid in response to pressure monitored by a sensor.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine D. Hopkins whose telephone number is (571) 272-9058. The examiner can normally be reached on Monday-Friday, 7 a.m.-3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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